2.1 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	August 17, 2013
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***Arthrex Univers Apex***
Common Name	Shoulder Prosthesis
Product Code -Classification Name	KWS
CFR	888.3660: Prosthesis, Shoulder, Semi-Constrained Metal/Polymer, Cemented HSD 888.3690: Prosthesis, Shoulder, Hemi-Humeral, Metal, Uncemented
Predicate Device	*K071032 / K103466: Arthrex Univers II Shoulder Prosthesis* *K060692 : Comprehensive Primary Shoulder Stems*
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Univers Apex.
Device Description	The Univers Apex is the humeral stem component of a shoulder prosthesis system. It consists of a stem, a trunion, an inclination block and pins and screws. All of the components are comprised of titanium. The Short Stem is identical to the existing Univers II Stem, except

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	for the overall length.
Intended Use	The Univers Apex is Indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or, other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.
Substantial Equivalence Summary	The Arthrex Univers Apex is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the Arthrex Univers Apex and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed devices are comprised of titanium. This material is substantially equivalent to the materials found in the predicate devices. The submitted mechanical testing data demonstrates that the fatigue strength of the proposed devices are comparable to that of the predicate device for the desired indications. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the Univers Apex is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
Ms. Courtney Smith
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

September 27, 2013

Re: K131633
Trade/Device Name: Arthrex Univers Apex
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: August 6, 2013
Received: August 7, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.5 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

Device Name: **Arthrex Univers Apex**

Indications For Use: K131633

The ***Arthrex Univers Apex*** is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or, other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices